

APPLICATION UNDER UNITED STATES PATENT LAWS

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Invention: AIR-IN-LINE AND PRESSURE DETECTION

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This is a:

- ☐ Provisional Application
- ☒ Regular Utility Application
- ☐ Continuing Application
 - ☒ The contents of the parent are incorporated by reference
- ☐ PCT National Phase Application
- ☐ Design Application
- ☐ Reissue Application
- ☐ Plant Application
- ☐ Substitute Specification
 - Sub. Spec Filed _____
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 - Sub. Spec. filed _____
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SPECIFICATION

AIR-IN-LINE AND PRESSURE DETECTION

[0001] This application is based on and claims priority from U.S. Provisional Patent Application No. 60/216,772, filed July 7, 2000.

Field of the Invention

[0002] The present invention relates to a system and methods of determining air content and pressure in fluid, especially in association with an infusion pump.

Background of the Invention

[0003] There is a need in the field for methods of measuring air content and pressure of a sample fluid. Particularly in an infusion pump, it is critical to determine the air content of the infusion fluid and the fluid pressure down stream of the outlet valve of the infusion pump.

Summary of the Invention

[0004] The present invention is directed in part to unique methods of content measurement of a sample fluid. The present invention is based on the discovery that volume change in a chamber, as the chamber transitions between negative and positive pressure relates to the air content in the chamber. In particular, in an infusion pump, the volume change of infusion fluid as it transitions between being under negative pressure and positive pressure within a cassette central chamber, *e.g.*, pumping chamber, relates to the air content in the infusion fluid. In addition, the present invention provides methods for determining pressure of a sample fluid.

Brief Description of the Drawings

[0005] These and other objects and advantages of the invention will become more apparent and more readily appreciated from the following detailed description of an exemplary embodiment of the invention taken in combination with the accompanying drawings, of which:

40 to apply positive pressure to the fluid in the cassette central chamber 80. The shuttle mechanism 40 is also operably linked to an optical position sensor 180. A suitable position sensor is described in patent application number 60/217,885, filed July 7, 2000, entitled “Optical Position Sensor and Position Determination Method”, to Carlisle, Kaplan and Kirkman, the entire contents of which are incorporated herein by reference. A processor 220 is connected to motor 140 and the position sensor 180.

[0012] FIG. 2 is a diagram illustrating a cross-sectional view of a cassette assembly 20. The cassette assembly 20 contains an inlet valve 200, an outlet valve 210, a cassette central chamber 80, and a cassette piston 60. Cassette piston 60 is connected to shuttle 40.

[0013] In operation, the motor 140 is activated in one direction to withdraw the cassette piston 60 against the force of spring 120 via cam 160, creating a relative vacuum in the cassette central chamber 80 and pulling fluid through a one-way passive inlet valve 200 into the cassette central chamber 80. During this fill stroke, the pressure in the cassette central chamber 80 is negative, *e.g.*, between 0 and –10 psi. The amount of negative pressure depends on the withdrawal speed of the piston, fluid resistance, fluid viscosity, etc. Once the cassette piston 60 has been withdrawn, cam 160 disengages from the shuttle 40, enabling the spring mechanism 120 to urge shuttle 40 to drive piston 60 into the cassette central chamber 80. The pressure in the chamber then moves from a negative value through zero to a positive value. The one-way passive inlet valve 200 is now fully closed. The positive pressure in the cassette central chamber 80 is typically between +2 and +7 psi depending on the spring force applied to the cassette piston 60 through the shuttle 40 which is directly related to the length of the withdrawal stroke, *e.g.*, the further the withdrawal stroke the stronger the spring force.

[0014] In a closed cassette central chamber, the volume changes as a function of cassette central chamber pressure. In theory, when the cassette central chamber 80 is closed and contains only liquid, *i.e.*, air free fluid, the cassette central chamber is not compressible, thus no volume change occurs. Nevertheless in practice, a “base volume change” exists when the chamber contains just air free fluid (as shown in Figure 3). Such “base volume change” is irrelevant to the air content in the fluid and is mostly due to system designs such as the shape of a sealing member of the cassette piston 60 or the flexing of elastomeric inlet and outlet valve elements connected to the cassette central chamber 80.

[0015] For example, the cassette piston 60 in the cassette central chamber 80 acts as a nearly ideal piston when under positive pressure from the spring mechanism 120; thus a change in the axial position of the piston represents a fluid volume change in the cassette central chamber. Nevertheless, when cassette central chamber pressure changes from negative to positive, the shape of a sealing member of the cassette piston changes and results in piston travel without any change in central chamber fluid volume. This amount of travel contributes to the “base volume change”; it is significant, however, that this travel is a relative constant of the system design and does not change over time. In addition, the elastomeric valve elements connected to the cassette central chamber have some inherent displacement determined by their geometry and material properties. When under pressure, these elements move and to an insignificant degree, continue to move (creep) over time. The movement of these elements also contributes to the “base volume change”.

[0016] The “base volume change” of the cassette central chamber 80 can be determined by detecting the volume change of a control fluid under the pressure change of the cassette central chamber. The volume change can be measured by determining the change of shuttle position, *i.e.*, the piston travel position when the cassette central chamber pressure changes from negative to positive. The change of shuttle position is determined by the precision position sensor 180 linked to the shuttle mechanism 60. For example, one can compare the shuttle position in two states: the peak position during piston withdrawal and the shuttle position after the spring pressure is applied (as shown in Figure 4). This net displacement change of the shuttle position as a result of the pressure change in the cassette central chamber 80 filled with control fluid is a measure of the “base volume change” of the system 100, *e.g.*, the volume change that is inherent in the system 100.

[0017] In one embodiment, the “base volume change” of a control fluid is determined more than once and statistically conservative limits of “base volume change”, *e.g.*, lower than average, is selected as the “base volume change” for calculating the fluid air content. In another embodiment, the base volume change of a control fluid for a sample infusion fluid is determined by measuring the median volume change of more than one sample of the same infusion fluid, *e.g.*, over more than one fill stroke, resulting from the pressure change of the cassette central chamber. In yet another embodiment, the base volume change is the median volume change of an infusion fluid over eleven (11) contiguous fill strokes, and is updated or

modified periodically throughout an infusion therapy; and such base volume change is used to measure the sample fluid air content of the same infusion fluid.

[0018] In a closed cassette central chamber, *e.g.*, both inlet and outlet valves are closed, any cassette central chamber volume-versus-pressure changes above the “base volume change” are interpreted as volume changes in the cassette central chamber due to the presence of air (as shown in Figure 3). The air content of fluid contributes to the total volume change of the cassette central chamber and is proportional to the total volume change, *e.g.*, sample volume change minus the base volume change.

[0019] For example, one can fill the cassette central chamber 80 with a sample fluid until the volume (gVolMax) in the chamber is greater than the desired volume of fluid to be delivered in a single pump stroke (gVdue) plus the “base volume change” (Vbase). During the fill cycle, the fill volume can be monitored through the piston position, *i.e.*, the shuttle position which is determined by the optical position sensor 180. As a result of the geometry and design of the cassette assembly 20, there is a linear relationship between the shuttle position and the fill volume. Once the fill volume (gVolMax) is achieved, the motor direction is reversed so that the shuttle 40 falls off the cam 160 and rides freely on the spring mechanism 120. Similarly the end-diastolic volume (gVolEnd) can be determined from the stabilized shuttle position after the cam 160 releases shuttle 40. The sample volume change is the difference between the gVolMax and gVolEnd. The air content of the sample fluid is calculated in processor 220 as follows:

[0020] Air content (Volair) ~ Sample volume change – Base volume change

[0021] ~ (gVolmax-gVolEnd) – Base volume change

[0022] The air content measured according to the present invention is independent of the size and shape of the air bubble contained in a sample fluid, *e.g.*, the air content includes the content of big bubbles, small bubbles, integrated bubbles, and unintegrated bubbles.

[0023] In one embodiment, the effective amount of fluid that is pumped out of cassette central chamber 80 is calculated based on the air content of a sample fluid. For example, for a given stroke, the effective amount of fluid that is infused is calculated in processor 220 as follows:

[0024] effective amount of fluid infused $\sim gVol_{max} - Vol_{air}$

[0025] In another embodiment, the proportion of air content and volume content in a given stroke is calculated directly on the change of position of the piston. Specifically the proportion is calculated in processor 220 as follows:

[0026] proportion of air/fluid content = (position change due to pressure change)/(max. position under neg. pressure)

[0027] The processor 220 adjusts subsequent fluid flow rate based on the air/fluid content proportion in a given stroke to compensation for the air content detected in a sample fluid.

[0028] In yet another embodiment, processor 220 compares the air content of a sample fluid to a predetermined value stored in the processor 220; the processor 220 activates an alarming device if the air content of the sample fluid is close to or beyond the predetermined value. Alternatively, the processor 220 activates an alarming device as well as shuts down the out flow of sample fluid from the cassette central chamber 80, *e.g.*, closes the outlet valve 210 of the cassette central chamber 80 and shuts down infusion process by the fluid delivery system 100.

[0029] According to another feature of the invention, sample fluid continuously passes through cassette central chamber 80 and the air content of the sample fluid is determined at different time points and stored in processor 220. The processor 220 calculates accumulated air content of the sample fluid by adding the air content values collected at different time points. Such accumulated air content over a period of time is compared to a threshold air content value stored in the processor 220; the processor 220 triggers a notifying device, *e.g.*, an alarm, if the accumulated air content is close or beyond a predetermined limitation. Alternatively, the processor 220 activates a notifying device as well as shuts down the out flow of sample fluid from the cassette central chamber 80, *e.g.*, closes the outlet valve 210 of the cassette central chamber 80 and shuts down infusion process by the fluid delivery system 100.

[0030] In one embodiment, the outlet pressure of the cassette central chamber, *e.g.*, the blood pressure of a mammal such as a human connected to the infusion pump is monitored. For example, during the fluid displacement, the outlet valve 210 of the cassette

